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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,080	04/26/2001	Philippe J. Goix	A-69516/AJT	9621
7590		07/14/2004		
Aldo J. Test FLEHR HOHBACH TEST ALBRITTON & HERBERT LLP Four Embarcadero Center, Suite 3400 San Francisco, CA 94111-4187			EXAMINER GABEL, GAILENE	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/844,080	Applicant(s) GOIX ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-38 is/are pending in the application.
- 4a) Of the above claim(s) 12-33 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 and 3-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 4/18/04 is acknowledged and has been entered. Claims 1, 9, and 35 have been amended. Claims 12-33 and 38 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1 and 3-38 are pending. Claims 1, 3-11, and 34-37 are under examination.

Claim Objections

2. Claims 5-7, 10, and 11 are objected to for depending from a cancelled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 35-37 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reason of record.

Claim 35, preamble, is non-idiomatic and, therefore, confusing in reciting, "which includes". The phrase "which includes" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by other elements

included therewith), thereby rendering the scope of the claim unascertainable. Perhaps Applicant intends the term, "comprising".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3, 5, 8, and 34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Goix (WO 98/57152) in view of D'Autry (Derwent Accn. No. 1973-26106U or US Patent 3,827,304) for reasons of record.
5. Claims 6 and 9-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of D'Autry (Derwent Accn. No. 1973-26106U or US

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Patent 3,827,304) as applied to claims 1-3, 5, 8, and 34 above, and further in view of Hirako (US 5,135,302) for reasons of record.

6. Claims 35-37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of D'Autry (Derwent Accn. No. 1973-26106U or US Patent 3,827,304) as applied to claims 1-3, 5, 8, and 34 above, and further in view of Bernstein et al. (US 5,478,750) for reasons of record.

7. Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of D'Autry (Derwent Accn. No. 1973-26106U or US Patent 3,827,304) as applied to claims 1-3, 5, 8, and 34 above, and further in view of Mochida et al. (US 5,147,607) for reasons of record.

8. Claim 7 stands rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Goix (WO 98/57152) in view of D'Autry (Derwent Accn. No. 1973-26106U or US Patent 3,827,304) as applied to claims 1-3, 5, 8, and 34 above, and further in view of von Behrens et al. (US 5,378,633) for reasons of record.

Response to Arguments

9. Applicant's arguments filed 4/19/04 have been fully considered but they are not persuasive.

A) Applicant argues that the combination of Goix with D'Autry does not suggest or render obvious the claimed invention. Specifically, Applicant argues that Goix teaches use of a pump such as a syringe pump, connected to one end of a capillary for injecting a test sample into and through the capillary whereas in the present invention,

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sample is drawn through the capillary [using the pump]. Applicant specifically contends that there is an important difference between the two methods of causing the sample to flow through the capillary.

In response to applicant's arguments against the Goix reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Claim 1 recites an apparatus ... comprising ... a pump connected to a first end of a capillary and Goix teaches a pump, such as a syringe pump connected (coupled) to the first end of the channel for drawing sample into the second end of the capillary channel in page 6, lines 18-26. The teaching of pump system by D'Autry is incorporated with the apparatus as taught by Goix only for the teaching of a [second] end of the capillary being suspended for immersion into a sample so that the pump draws the sample into the first end of the capillary channel.

In as far as Applicant's contention that the pump in the claimed invention is used "to draw sample into and through the capillary" and the pump as taught by Goix is used to inject the sample into and through the capillary, a recitation of the intended use of the claimed "pump" must result in a structural difference between the claimed invention and the combined prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art pump of Goix as combined with D'Autry is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See

In re Casey, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Additionally, in as far as the differences between the method described in Applicant's specification and that taught by Goix, i.e. methods of causing sample to flow through the capillary, it is noted that the claims are drawn to an apparatus rather than a method of using the apparatus. Accordingly, Applicant's argument on the claimed apparatus is not on point.

B) Applicant argues that in Goix's apparatus, either a disposable pump is required or a thorough washing of the pump is required between sample analyses. Applicant contends that in the claimed invention, by drawing sample into a suspended end of a capillary as in the claimed invention, mixing or cross contamination is avoided.

In response, the claimed apparatus does not recite the feature upon which applicant relies, i.e. a disposable pump is not required, a thorough washing is not required [while in use in a method]. Hence, Applicant's argument encompassing methods used on the claimed apparatus is not on point. In as far as Applicant's contention that the pump in the claimed invention is used "to draw sample into and through the capillary", a recitation of the intended use of the claimed "pump" must result in a structural difference between the claimed invention and the combined prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art pump of Goix as combined with D'Autry is capable of performing the intended use, then it meets the claim.

C) Applicant argues that the claimed invention calls for a pump connected to the first end of the capillary for drawing sample into the second end of the channel; such an arrangement is not taught nor suggested by Goix.

In response, Goix teaches a pump system connected (coupled) to a first end of a capillary channel. The teaching of pump system by D'Autry is incorporated with the apparatus as taught by Goix only for the teaching of a [second] end of the capillary being suspended for immersion into a sample so that the pump draws the sample into the first end of the capillary channel. D'Autry teaches drawing repetitive liquid samples for analysis using the described pump system. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate a capillary and pump such as in the analytical apparatus taught by D'Autry into the apparatus as taught by Goix because D'Autry specifically taught that such configuration provides many different advantages including accuracy from elimination of carry-over contamination, reduction in the volume of sample required, reduction in time required for analysis, and adaptability with automation. Accordingly, one of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the capillary and pump as taught by D'Autry into the apparatus of Goix. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

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generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

D) Applicant argues that D'Autry does not teach or suggest a capillary tube in which a predetermined length is illuminated to cause particles in the illuminated length to fluoresce.

In response to applicant's arguments against the D'Autry individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Goix teaches an apparatus comprising an elongate cylindrical capillary channel with a predetermined internal cross-sectional area configured to admit particles one at a time, i.e. singulate, as a predetermined sample volume passes through analysis area, a pump for drawing sample containing the particles through the channel and flowing the particles along the capillary channel into its other end. The teaching of pump system by D'Autry is incorporated with the apparatus as taught by Goix only for the teaching of a [second] end of the capillary being suspended for immersion into a sample so that the pump draws the sample into the first end of the capillary channel. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate a capillary and pump such as in the analytical apparatus taught by D'Autry into the apparatus as taught by Goix because D'Autry specifically taught that

such configuration provides many different advantages including accuracy from elimination of carry-over contamination, reduction in the volume of sample required, reduction in time required for analysis, and adaptability with automation. Accordingly, one of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the capillary and pump as taught by D'Autry into the apparatus of Goix.

E) Applicant argues that D'Autry discloses sample handling method including the steps of intercommunicating the top of the analysis vessel with a sample holding container with a first conduit, etc., and operating the pump in a first direction of operation for a predetermined period of time, etc. Applicant then contends that it is not necessary for D'Autry to fill the analysis vessel in order to move liquid through the vessel, and the amount of liquid required to obtain an uncontaminated sample is greatly reduced. Applicant, therefore, argues that there is no suggestion by D'Autry of having a sample fluid flow past an analyzing volume in a capillary by a pump-connected to one end of a capillary.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., sampling handling methods as described by D'Autry) are not recited in the rejected claims. The claimed invention specifically recites and describes an apparatus ... comprising ... a pump connected to a first end of a capillary Accordingly, Applicant's arguments are not on point.

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
July 6, 2004

gg

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
7/12/04